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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,252	11/28/2006	David John Chapman-Jones	51407/P029US/10605267	9077
29053 7590 07/14/2010 FULBRIGHT & JAWORSKI L.L.P 2200 ROSS AVENUE SUITE 2800 DALLAS, TX 75201-2784			EXAMINER PATEL, SHEFALI DILIP	
			ART UNIT 3767	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,252	Applicant(s) CHAPMAN-JONES, DAVID JOHN	
	Examiner SHEFALI D. PATEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,29-39 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,29-33,35-39 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 12, 2010, has been entered.

Acknowledgments

2. In the reply, filed on May 12, 2010, Applicant amended claims 29 and 32.
3. In the final rejection of February 5, 2010, Examiner rejected claims 31, 32, and 36 under 35 USC 112, 2nd paragraph, as being indefinite with respect to insufficient antecedent basis for claim terms. With respect to claims 31 and 36, Applicant states that reciting "the frequency" is appropriate without first reciting "a frequency" since frequency is inherent to alternating current. Rejection is withdrawn. With respect to claim 32, Applicant amended the claim to remove "and/or frequency". Rejection is withdrawn.
4. Currently, claims 26, 29-33, 35-39, and 48 are under examination.

Claim Objections

5. Claim 37 is objected to because of the following informalities:

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In regards to claim 37, the limitation “controlling operation of the control unit” should be changed to “control operation of the control unit”.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 29 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Boetzkes (US 5,038,780).

In regards to claim 29, Boetzkes teaches a device (Figures 1-3) for treating tissue, the device comprising:

- a. a dressing (cast) for applying to a treatment area (treatment site [12]) of said tissue (column 5, lines 57-60)
- b. a pair of electrodes (electrodes [14]) affixed to a treatment surface of the dressing (column 5, lines 57-60)
- c. a control unit (control and output subsystem [18]) for passing alternating current to the treatment area [12] via the electrodes [14] and for constantly varying the amplitude of the alternating current to electrically stimulate and repair said tissue (Abstract)(column 1, lines 32-35)

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In regards to claim 35, Boetzkes teaches that the control unit [18] comprises: a housing [18] and electronic circuitry (circuit [34]) in the housing connected to the pair of electrodes [14] (Figures 1-2).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 26, 30, 31, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boetzkes, as applied to claims 29 and 35 above, and further in view of Claude (US 4,982,742).

In regards to claim 26, Boetzkes is silent about whether the control unit [18] and the dressing (cast) are integrated with each other. Claude teaches a device (Figures 1-5), wherein a control unit (circuit strip [26] containing circuitry [28]) and a dressing (bandage layers [12][14]) are integrated with each other. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the control unit and the dressing, of the device of Boetzkes, to be integrated with each other, as taught by Claude, as the providing the dressing and the control unit in a self contained package will keep the dressing sterile and protect the internal battery of the control unit from discharging before use (column 1, lines 17-23).

In regards to claim 30, Boetzkes does not teach that the alternating current is varied between 50 and 500 microamps, since Boetzkes only teaches that an alternating current of approximately 5 milliamperes is produced (column 5, lines 13-15). Claude teaches a device

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(Figures 1-5), wherein the current ranges from 100 to 1000 microamperes (Abstract). But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the alternating current to be varied between 50 and 500 microamps, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (current range) involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 31, Boetzkes does not teach that the frequency of the alternating current is varied between 10 and 900 hertz, since Boetzkes only teaches a frequency of 50 kilohertz (column 5, lines 30-37). Claude teaches a device (Figures 1-5) wherein the frequency ranges from 10 to 50 hertz (Abstract). Hence, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the frequency of the alternating current to be varied between 50 and 500 microamps, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (frequency) involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 39, Boetzkes does not teach a removable tab including a metallic strip that connects the electrodes and only allows current to pass once the tab is removed. Claude teaches a device (Figures 1-5) wherein a removable tab (pull away tab [52]) is electro-mechanically connected between a power source [50] and a ground point on the control unit [28]. When the tab [52] is intact, the power source [50] is connected to ground point and energization of the control unit [28] does not occur. Once the tab is removed, the electrical connection between the power source [50] to ground point is broken, and as result, the power source [50] drives the control unit [28] to generate current toward the electrodes (column 3, lines 37-45). It

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would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device, of Boetzkes, with a removable tab, as taught by Claude, as the removable tab will provide a means for controlling the energization of the control unit to allow for or prevent delivery of current to the electrodes (column 3, lines 37-45). Further, Claude is silent about whether the removable tab [52] is metallic. But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the removable tab to include a metallic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Also, it is common knowledge to those of ordinary skill in the art to choose a material that has sufficient conductivity, such as a metal, in electrical energy applications.

10. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boetzkes, as applied to claim 29 above.

In regards to claim 32, Boetzkes is silent about whether the time period between each variation of amplitude and/or frequency is 0.1 s. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the time period between each variation of amplitude and/or frequency to be 0.1 s, since it has been held that discovering the optimum value of a result effective variable (time period) involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

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11. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boetzkes, as applied to claim 29 above, and further in view of Grey et al (US 5,397,338).

In regards to claim 33, Boetzkes does not teach that the alternating current has a ramp waveform, since Boetzkes teaches a square waveform. Grey et al teaches a device (Figures 1-9) wherein the current has a ramp waveform (column 9, lines 18-21). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the waveform, of the device of Boetzkes, to have a ramp waveform, as taught by Grey et al, as an obvious design choice to the user, as a ramp waveform is one waveform shape that will allow amplitude, pulse width, or frequency modulation (column 9, lines 8-21).

12. Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boetzkes, as applied to claim 35 above, and further in view of Fischell et al (US 2002/0099412).

In regards to claim 36, Boetzkes is silent about whether the electronic circuitry comprises memory storing at least one program for determining the amplitude, frequency and waveform of alternating current supplied to the electrodes. Fischell et al teaches a device wherein electronic circuitry comprises memory storing at least one program for determining the amplitude, frequency and waveform of current supplied to the electrodes (paragraphs [0013][0021]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device, of Boetzkes, with a memory storing at least one program for determining the amplitude, frequency and waveform of current supplied to the electrodes, as taught by Fischell et al, as storing the amplitude, frequency, and waveform of current supplied to the electrodes in memory will allow patient data to be recorded for future use to enhance the

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detection of a patient disorder and to optimize the device responses for stopping such a patient disorder (paragraph [0021]).

In regards to claims 37 and 38, in a modified device of Boetzkes and Fischell et al, Boetzkes does not teach a memory. Fischell et al teaches an i/o port connected to the electronic circuitry, such that an external device can wirelessly connect to the control unit via the i/o port and update the memory and control operation of the control unit (paragraphs [0170][0171]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the modified device, of Boetzkes and Fischell et al, with an i/o port, as taught by Fischell et al, as the i/o port will wirelessly receive physician commands from the physician's external equipment and will read and send back disorder event related data previously stored in the memory back to the physician's external equipment (paragraph [0170][0171]).

13. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boetzkes, as applied to claim 29 above, and further in view of Johnson et al (US 2002/0099425).

In regards to claim 48, Boetzkes does not teach that the control unit is also for constantly varying the frequency of the alternating current. Johnson et al teaches a device wherein a control unit constantly varies the frequency of the alternating current (paragraph [0007]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the control unit, of the device of Boetzkes, to constantly vary the frequency of the alternating current, as taught by Johnson et al, as such will allow the user to customize treatment regimens for particular treatment effects for particular patients by varying how often electrical current is applied to the patient during the treatment regimen (paragraph [0036]).

Response to Arguments

14. Applicant's arguments with respect to claims 26, 29-33, 35-39, and 48 have been considered but are moot in view of the new ground(s) of rejection, based on the insertion of subject matter ("of the alternating current to electrically stimulate and repair said tissue") not previously presented in the claims into independent claim 29.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
07/12/2010

/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767